

**REMARKS**

Claims 1-55 are pending in this application. Claims 1-23, 25, 30-33, and 36-40 are currently amended. Claims 27-29, 34-35, 41-46, 47-50 are canceled. Reconsideration and allowance of all of the pending claims is respectfully requested.

No new matter is being introduced by the present amendments. The amendments to the claims are editorial in nature and do not change the scope of the claims. Accordingly, entry of this amendment is respectfully requested.

**Claim Rejections - 35 U.S.C. §101**

Claims 47-50 are rejected under 35 U.S.C. §101 as improper process claims. Claims 47-50 are canceled by this amendment. Accordingly, withdrawal of this rejection is respectfully requested.

**Claim Rejections – 35 U.S.C. §112, second paragraph**

Claims 1-22, 25-43, and 51-55 are rejected under 35 U.S.C. §112, second paragraph as indefinite. For the following reasons, the Applicants respectfully traverse.

Claims 25 and 27-43 are rejected over the use of the term "medicament." Claims 25 and 27-41 are currently amended to address this rejection. Accordingly withdrawal of this rejection is respectfully requested.

Claim 26 is rejected because the claims are asserted to be self-conflicting. Claim 26 is canceled by this amendment. Accordingly withdrawal of this rejection is respectfully requested.

Claims 1-22 are rejected over the term "hydrate of those." Claims 1-22 are currently amended to address this rejection. Accordingly withdrawal of this rejection is respectfully requested.

Claims 27-29 and 34-35 are rejected as vague and ambiguous. Claims 27-29 and 34-35 are canceled by this amendment. Accordingly withdrawal of this rejection is respectfully requested.

Claims 51-53 are rejected over the term "6-deoxy 11107." The Applicants respectfully traverse this rejection because the 6-deoxy 11107 compounds are well defined in the specification beginning at page 75, line 17 up to page 93. Accordingly withdrawal of this rejection is respectfully requested.

Claims 52 and 54-55 are rejected over the term "strain-A-1543 (FERM BP-8442)." The Applicants respectfully traverse this rejection, because the term "strain-A-1543" is defined as: FERM BP-8442, which is the international accession number of the microorganism. Accordingly, withdrawal of this rejection is respectfully requested.

Claim 53 is rejected over the term "biologically converting." The Applicants respectfully traverse this rejection, because the term "biologically converting" is defined as microbially converting 6-deoxy 11107B to 6-deoxy 11107 by culturing a microorganism capable of chemically converting 6-deoxy 11107B to 6-deoxy 11107, in a medium capable of chemically converting 6-deoxy 11107B. Accordingly, withdrawal of this rejection is respectfully requested.

## **Claim Rejections – 35 U.S.C. §112, first paragraph**

### *1. Written description*

Claims 1-22, 44-46, and claim 51 are rejected under 35 U.S.C. §112, first paragraph as not meeting the written description requirement. For the following reasons, the Applicants respectfully traverse.

Claims 1-22 are currently amended to address this rejection. Claims 44-46 are canceled. Accordingly, withdrawal of these rejections is respectfully requested.

With regard to claim 51, the Applicants respectfully submit that the claim is fully described in the specification as filed. "There is a strong presumption that an adequate written description of the claimed invention is present when the application is filed." MPEP §2163 citing *In re Wertheim*, 541 F.2d 257, 263, 191 USPQ 90, 97 (CCPA 1976) ("we are of the opinion that the PTO has the initial burden of presenting evidence or reasons why persons skilled in the art would not recognize in the disclosure a description of the invention defined by the claims").

Specific conditions for the method of claim 51 are given in the specification. See pages 75-93 of the specification. Variations of the method of claim 51 would be well understood by one of skill in the art. One of skill in the art would immediately and completely understand the method of claim 51. The standard for meeting the written description requirement is given in the MPEP as follows:

"Possession may be shown in a variety of ways including description of an actual reduction to practice, or by showing that the invention was "ready for patenting" such as by the disclosure of drawings or structural chemical formulas that show that the invention was complete, or by describing

distinguishing identifying characteristics sufficient to show that the applicant was in possession of the claimed invention."

MPEP §2163, p. 2100-173. The present specification clearly demonstrates that the Applicants were in possession of the invention of claim 51 through a description of an actual reduction to practice and a disclosure of specific conditions for the reaction. The Office Action provides no reasons or explanation why one skilled in the art would not recognize in the disclosure a complete description of claim 51. Accordingly, the Office has not met its burden of presenting evidence or reasons why one skilled in the art would not find a complete description of claim 51 in the disclosure. Accordingly, withdrawal of this rejection is respectfully requested.

## *2. Enablement*

At section 6 of the Office Action, claims 51-55 are rejected under 35 U.S.C. §112 as failing to comply with the enablement requirement. For the following reasons, the Applicants respectfully traverse.

The Office Action asserts that claims 51-55 recite a genus, and that there is no record of any deposit in the disclosure. However, as described on page 79, lines 10-20 species of the genus have been internationally deposited.

In addition, the Applicants respectfully submit that the full scope of the claims is fully enabled. In the present case, specific species of the claimed genus are named and have been internationally deposited. "[T]o provide effective incentives, claims must adequately protect inventors. To demand that the first to disclose shall limit his claims to what he has found will work or to materials which meet the guidelines specified for "preferred" materials in a process such as the one herein involved would not serve the constitutional purpose of promoting progress

in the useful arts." MPEP §2164.08, citing *In re Goffe*, 542 F.2d 564, 567, 191 USPQ 429, 431 (CCPA 1976).

With regard to the amount of experimentation that is required "The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed." MPEP §2164.06, citing *In re Colianni*, 561 F.2d 220, 224, 195 USPQ 150, 153 (CCPA 1977).

It is respectfully submitted that it would not require undue experimentation for one skilled in the art to practice the present invention with the full scope of the streptomyces genus. The Examiner has provided no persuasive evidence to the contrary. Accordingly, the Applicants respectfully submit that this rejection must now be withdrawn.

At sections 7, 8, and 9 of the Office Action, claims 44, 45, and 46 are also rejected under 35 U.S.C. §112 as not meeting the enablement requirement. Claims 44-46 are canceled by this amendment. Accordingly, withdrawal of these rejections is respectfully requested.

### CONCLUSION

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact J. Mark Konieczny (Reg. No. 47,715) at the telephone number below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

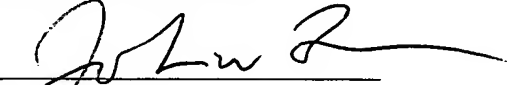
Application No. 10/522,731  
Amendment dated July 7, 2006  
Reply to Office Action of January 9, 2006

Docket No.: 0152-0702PUS1

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. §§ 1.16 or 1.17; particularly, extension of time fees.

Dated: July 7, 2006

Respectfully submitted,

By 

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